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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,226	05/21/99	LENTZ M	LEN-101-CIP

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
3762	5

DATE MAILED: 02/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/316,226	Lentz
Examiner	**Group Art Unit**
William Noggle	3762

☒ Responsive to communication(s) filed on *Aug 30, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-27* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,5,11-15,20-24,27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713).

As to claims 1,2, and 12, Lentz (4,708,713) had disclosed a method and system for inducing an immune response against tumors comprising removing components in the blood having a molecular weight of 200,000 Daltons or less (page 2, lines 8-33). Lentz had also disclosed the system having inlet and outlet means for connection to a pump and tubing to recirculate the blood of a patient through the device (see figure 1). Lentz had not disclosed removing only components present in the blood having a molecular weight of 120,000 Daltons or less. However, Lentz (4,708,713), discloses the claimed invention except for the 120,000 versus the 200,000 Dalton cut off. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the upper range value from 200,000 to 120,000 Daltons, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

As to claims 3 and 4, the method of claim 1 is obvious in light of Lentz. Lentz had also disclosed the components being removed from one blood volume or in multiple treatments (page 7, lines 50-60).

As to claims 5 and 21, the system and method of claims 12 and 1 is obvious in light of Lentz. Radiation treatment was well known in the art at the time the invention was made. It was well known in the art at the time the invention was made to combine radiation treatment with another form of cancer treatment.

As to claim 11, the method of claim 1 is obvious in light of Lentz. The use of vaccine against a transformed, infected, or diseased tissue was well known in the art at the time the invention was made, and the use of a vaccine would have been an obvious choice to a person skilled in the art, for example a medical doctor, at the time the invention was made.

As to claims 13-15, the system of claim 12 is obvious in light of Lentz. The criticality of the type of filter used in the system was not specified by the applicant, therefore the filter type would be an obvious design choice to a person skilled in the art at the time the invention was made. Obvious design choices do not hold any patentable weight. Lentz had also disclosed the pore size of the filter medium as being between .02 and .05 microns and between .04 and .08 microns (page 10, claims 4 and 5).

As to claim 20, it was well known in the art to separate blood cells from plasma to treat the remaining plasma. It would have been obvious to a person having ordinary skill in the art to

separate the blood cells, while treating the plasma, because this would detract from the risk of damaging the blood cells.

As to claim 22, making a kit from the method and apparatus would have been obvious to a person having ordinary skill in the art at the time the invention was made. See arguments to claims 1,5, and 12.

As to claims 23,24, and 28, Lentz had not disclosed a kit with procoagulant or anti-angiogenic compounds or alkylating agents, doxyrubicin, carboplatinum, cisplatinum, or taxol. However, all of these compounds can be found in a medical laboratory, so the mere grouping of these compounds into a kit would have been obvious to a person having ordinary skill in the art.

As to claim 27, see arguments to claim 22, and chemotherapeutic treatment was well known in the art at the time the invention was made. It was well known in the art at the time the invention was made to combine chemotherapeutic treatment with another form of cancer treatment.

Claims 6,25,26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Wolpe (5,861,483).

As to claims 6,25,26, and 29, Lentz had disclosed a device for removing only components present in the blood having a molecular weight of 120,000 Daltons or less, see arguments for claim 1. Lentz had also disclosed the use of an anticoagulant through the device, page 3, lines 66-68. Lentz had not disclosed the device being in a kit and including an agent selected from the group consisting of anti-angiogenic compounds, procoagulant compounds, cytokines, chemotherapeutic agents, and radiation, in a dosage formulation. However, Wolpe had disclosed the need for

stimulatory cytokines, specifically erythropoietin, to maintain a fully functional immune system, page 1, lines 25-45. The presumed mechanism which Lentz's invention is based on is removing immune inhibitors and letting the body's immune system combat the tumor. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to add a dose of erythropoietin to a kit including Lentz's device, because erythropoietin works to maintain a fully functional immune system, page 1, lines 25-45.

Claims 7-10 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz (4,708,713) in view of Chen et al. (Journal of Neuropathology and Experimental Neurology). The method of claim 1 is obvious in light of Lentz. Lentz had not disclosed the method as removing soluble TNF 1 and 2 receptors from the blood. However, Chen et al. had disclosed the conclusion that TNF receptors help to evade the immune response against a tumor, page 549. Therefore, it would have been obvious to a person skilled in the art at the time the invention was made to remove TNF 1 and 2 by means of ultrafiltration, because these elements help to evade the immune response against tumors. It was well known in the art to remove unwanted molecules from the bloodstream using an absorbent column where the affinity agent is an antibody for the unwanted molecules. It would have been obvious to a person having ordinary skill in the art to use this absorbent column with Lentz and Chen, because this would eliminate the unwanted molecules.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Noggle whose telephone number is (703) 308-4543.

WN

January 16, 2000

John G. Weiss
Supervisory Patent Examiner
Group 3700